

EXHIBIT S

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Buying Guides, Pulse Oximetry

How To Buy Pulse Oximeters For Your Medical Facility

Have you ever heard of keeping your finger on the pulse? Well, we're talking about using your patients' fingers to take their pulse, and measure their oxygen levels.

That's right. We're talking about pulse oximeters.

Your patients' oxygen levels are an important part of their care. Tracking the amount of oxygen in their bloodstream is another data point that can help you come to the proper diagnosis.

But where do you get them? Where is the best place to [buy pulse oximeters](#)? Well, today is your lucky day. That's exactly what we're going to cover in this article.

By the end of this, you'll know everything you need to know about a finger oximeter.

Read along with us!

Why Buy Pulse Oximeters

Well, as we mentioned above, your patients' oxygen levels can be an important part of their diagnosis. But, more recently, there's been an important link made between COVID-19 and pulse oximeters.

Since early on in the pandemic, medical professionals have noticed that patients can develop a condition known as "happy hypoxia." On the surface, patients with this condition look like nothing is wrong. But, when looking deeper, doctors discover that patients suffering from this condition have severely low oxygen levels.

How were they able to tell? By taking readings with a pulse oximeter.

Happy hypoxia is difficult to diagnose without any knowledge of a patient's blood oxygen levels. These levels need to be measured because the condition can be extremely dangerous. Patients can deteriorate suddenly without any prior warning signs. In the blink of an eye, these patients may need access to life-saving machinery that can support their breathing.

What Is A Pulse Oximeter?

You might be wondering "what exactly is a pulse oximeter." Most people are familiar with them, but if you're not, that's ok.

A pulse oximeter is a non-invasive medical tool that can clip to a patient's fingertip or earlobe. The device will measure the patient's heart rate, as well as how much oxygen is present in their blood. When medical professionals combine this information with other medical data, it enables them to make life-saving decisions about their patients.

By reading the heart rate and blood oxygen levels of their patients, doctors can decide if breathing support is necessary. This needs to be a quick decision since access to this equipment typically requires transferring the patient to a bigger hospital.

Who Needs A Pulse Oximeter?

During the current pandemic, sales of pulse oximeters are increasing in certain areas. Doctors send their patients home with one of these devices so they can monitor their patient's oxygen levels after discharge.

One concern, though, is that the devices may not be as accurate when they're sent home with patients. Part of the reason for this is that patients may not be using them properly. Another reason is that the device has difficulty reading oxygen levels through darker skin tones.

Regardless, the devices have been extremely helpful during COVID-19. A pulse oximeter can't diagnose COVID-19, but it can help patients significantly after they've been diagnosed.

A pulse oximeter can help a [COVID-19 patient](#) see when the level of oxygen in their blood is falling. This is important in people who are prone to developing more serious symptoms from a bout with COVID-19. This means the older sector of the population, as well as people with comorbidities.

This group also includes patients with serious conditions that may put them at higher risk. Those conditions would be any serious heart or lung problems.

How They Work

Pulse oximeters work by emitting two different wavelengths of light through a person's fingertip or earlobe. These lights shine through the outer layer of the skin and can report back on how much oxygen is currently in the bloodstream.

The device does this because different amounts of light are absorbed by oxygenated and deoxygenated blood.

People in good health usually have an oxygen saturation level of 95% to 100%. If oxygen saturation drops below 92% it could be a sign of serious illness. If someone is receiving a reading of 92% or below off of their pulse oximeter, they may need immediate medical care.

Treatment for people with low oxygen levels can vary from country to country. The exact procedure depends on where you are in the world, but it usually involves seeking more serious medical evaluation.

Improving Accuracy

When medical clinics buy pulse oximeters, they usually undergo clinical testing. This is a key step in testing the device's accuracy when reading oxygen levels.

These devices are available for purchase online. But people need to be wary when buying pulse oximeters themselves. Online prices can often be higher than what the device actually costs.

Buyers also need to be careful of very low-cost device options. Just because a device has low prices doesn't mean it's the best pulse oximeter. You want to make sure you're buying a device that has a government agency's approval. An example would be the FDA.

It's also important to be sure you're using medical-grade devices and not personal technology. We know we live in a technology age. Many smartphones and smartwatches offer pulse oximeters. But these devices don't give patients an accurate reading.

Buy Pulse Oximeters That Are Medical Grade

The most accurate readings you can find will be with a certified pulse oximeter device. Even then patients should still proceed with some amount of caution.

Even medical devices aren't 100% accurate all of the time. A study in the New England Journal of Medicine found that pulse oximeters can be [inaccurate up to 12% of the time](#) when used on dark skin tones. And 4% of the time when used on lighter skin.

This is why patients should never rely on pulse oximeter readings alone. Patients, and doctors alike, should be paying attention to symptoms. If a patient is experiencing confusion or an acute case of shortness of breath, they should seek medical attention. Even if they appear to have appropriate levels of oxygen in their blood.

The benefits of pulse oximeters far outweigh the inaccuracies. In fact, when a patient uses a pulse oximeter consistently over time, the device may help prevent serious medical conditions. Continual readings of blood oxygen levels can alert doctors of declining lung health in their patients before it's too late.

The Best Finger Pulse Oximeter

So, by now you might be wondering "what is the best finger pulse oximeter?" That's a great question. There are a wide variety of makes and models available on the market, so we understand it can be overwhelming.

If you need to [buy pulse oximeters](#), here are some of the best available for your medical clinic.

Contec CMS-50DL

One of the nicest features of this finger pulse oximeter is its FDA approval. The device is also suitable for patients of all ages. The one downside is its short battery life.

The Contec device also has premier accuracy when it comes to its readings. The CMS-50DL has been tested by researchers. They've concluded that the readings from the device are accurate enough to comply with ISO standards.

Zacurate Pro Series 500DL

This device from Zacurate rates as the best budget option available. The device is both accurate and reliable but doesn't boast any sort of rating or certification from a government health organization.

The 500DL reads oxygen levels and your heart rate. Both numbers display nicely on Zacurate's easy-to-read display screen.

While it does have longer battery life than the Contec device, it's not a suitable option for children. It's more appropriate for patients 12 years of age or older.

Wellue O2Ring

This is one of the more unique, cutting-edge devices. Instead of clipping to the patient's fingertip, the Wellue O2Ring is exactly that. A ring.

Patients can wear this ring on their thumb to get accurate oxygen and heart rate readings. Clinical studies have been able to prove that ring devices don't sacrifice any accuracy over their fingertip counterparts.

This device also leverages modern technology as it can pair with your mobile device via Bluetooth.

Since it can be comfortably worn around your finger, it's also a great option for patients who need to wear a pulse oximeter overnight. Doctors usually prescribe this for their patients dealing with sleep apnea or COPD.

The O2Ring also offers vibrating alerts. This is helpful if you're wearing the ring overnight. The vibration function is a way to gently alert you if oxygen levels fall too low. Patients may prefer this much more than a loud beeping alert.

The major drawback of this device is that it is more expensive than a standard finger oximeter.

That's A Wrap

There you have it. All the information you need to buy pulse oximeters. When it comes to monitoring your patient's health, it's one of the most important tools you can use. And the fact that it can gather all of that information, while still being non-invasive, makes it a vital part of any medical facility's toolbelt.

If you have any questions about medical monitoring devices, [Infinium is here](#) to help. We offer a variety of medical services and equipment and can consult you and your team on the best way to improve your medical facility's performance.

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Limitations of Pulse Oximeters

Pulse oximeters are a common medical device that is used to measure the oxygen saturation in a patient's blood. While it is a valuable tool, it does have some limitations

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EXHIBIT T

CORRESPONDENCE



Racial Bias in Pulse Oximetry Measurement

TO THE EDITOR: Oxygen is among the most frequently administered medical therapies, with a level that is commonly adjusted according to the reading on a pulse oximeter that measures patients' oxygen saturation. Questions about pulse oximeter technology have been raised, given its original development in populations that were not racially diverse.^{1,2} The clinical significance of potential racial bias in pulse oximetry measurement is unknown.

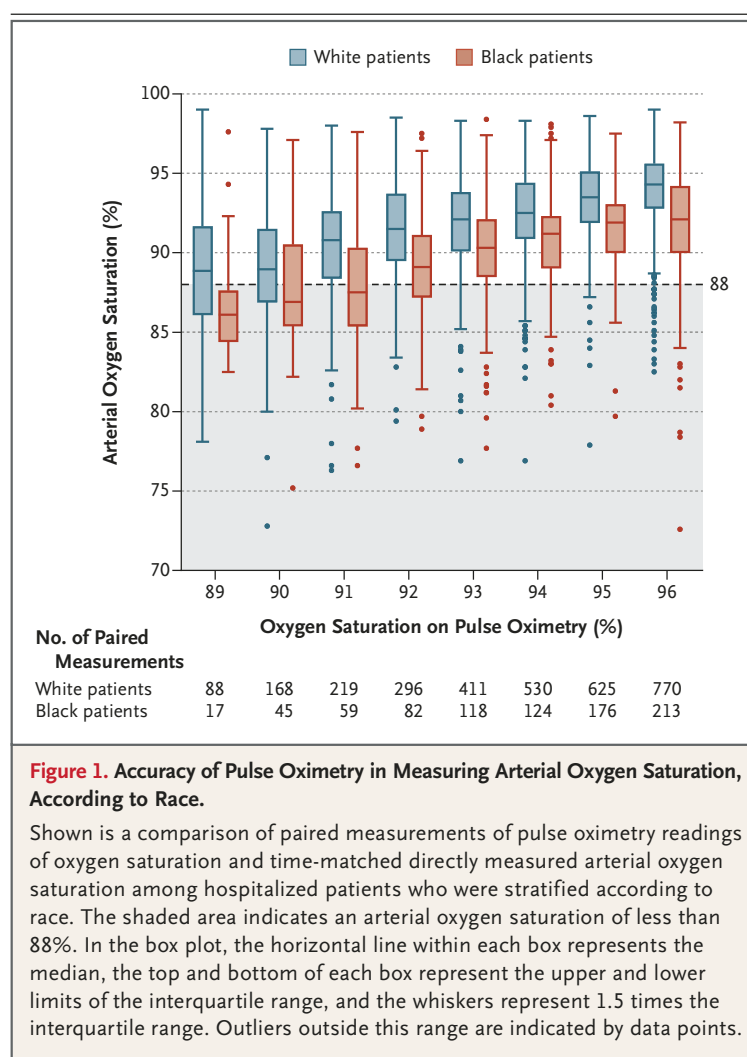
Our study involved adult inpatients who were receiving supplemental oxygen at the University of Michigan Hospital (from January through July 2020) and patients in intensive care units at 178 hospitals (from 2014 through 2015).³ We analyzed paired pulse oximetry measures of oxygen saturation and measures of arterial oxygen saturation in arterial blood gas, with all evaluations performed within 10 minutes of each other. To ensure that the arterial oxygen saturation was directly measured by co-oximetry, we limited analyses to measures of arterial blood gas that included carboxyhemoglobin and methemoglobin saturations.

We tested for occult hypoxemia (i.e., an arterial oxygen saturation of <88% despite an oxygen saturation of 92 to 96% on pulse oximetry) among patients who identified their race as Black or White. Since a low level of peripheral perfusion could lower the accuracy of oxygen saturation values,⁴ we also estimated the percentage of patients with occult hypoxemia after adjusting for age, sex, and cardiovascular score on the Sequential Organ Failure Assessment (SOFA) in the University of Michigan cohort. Additional details regarding the methods that were used in the study are provided in the Supplementary Appendix, available with the full text of this letter at NEJM.org.

We analyzed 10,789 pairs of measures of oxygen saturation by pulse oximetry and arterial oxygen saturation in arterial blood gas obtained from 1333 White patients and 276 Black patients in the University of Michigan cohort and 37,308 pairs obtained from 7342 White patients and 1050 Black patients in the multicenter cohort. In the University of Michigan cohort, among the patients who had an oxygen saturation of 92 to 96% on pulse oximetry, an arterial oxygen saturation of less than 88% was found in 88 of 749 arterial blood gas measurements in Black patients (11.7%; 95% confidence interval [CI], 8.5 to 16.0) and in 99 of 2778 measurements in White patients (3.6%; 95% CI, 2.7 to 4.7) (Fig. 1). The findings in the adjusted analyses were similar to those in the unadjusted analyses, with an arterial blood gas oxygen saturation of less than 88% in 11.4% (95% CI, 7.6 to 15.2) of the measurements in Black patients and in 3.6% (95% CI, 2.5 to 4.6) of those in White patients. Results were

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also consistent after the exclusion of patients with an elevated carboxyhemoglobin level or diabetes. (Details are provided in the Supplementary Appendix.)

In unadjusted analyses, the area under the receiver-operating-characteristic curve for detecting an arterial blood gas oxygen saturation of less than 88% according to the oxygen saturation on pulse oximetry was 0.84 (95% CI, 0.81 to 0.87) among Black patients and 0.89 (95% CI, 0.87 to 0.91) among White patients ($P=0.003$). In the multicenter cohort, the unadjusted analyses involving patients with an oxygen saturation of 92 to 96% on pulse oximetry showed an arterial blood gas oxygen saturation of less than 88% in 160 of 939 measurements in Black patients (17.0%; 95% CI, 12.2 to 23.3) and in 546 of 8795 measurements in White patients (6.2%; 95% CI, 5.4 to 7.1).

Thus, in two large cohorts, Black patients had nearly three times the frequency of occult hypoxemia that was not detected by pulse oximetry as White patients. Given the widespread use of pulse oximetry for medical decision making, these findings have some major implications, especially during the current coronavirus disease 2019 (Covid-19) pandemic. Our results suggest that reliance on pulse oximetry to triage patients and adjust supplemental oxygen levels may place Black patients at increased risk for hypoxemia. It is important to note that not all Black patients who had a pulse oximetry value of 92 to 96% had occult hypoxemia. However, the variation in risk according to race necessitates the integration of pulse oximetry with other clinical and patient-reported data.

In device applications, the Food and Drug Administration requires reporting of demographic subgroups to mitigate risk. However, our findings highlight an ongoing need to understand and correct racial bias in pulse oximetry and other forms of medical technology.

Michael W. Sjoding, M.D.

Robert P. Dickson, M.D.

Theodore J. Iwashyna, M.D., Ph.D.

Steven E. Gay, M.D.

Thomas S. Valley, M.D.

University of Michigan Medical School

Ann Arbor, MI

msjoding@umich.edu

A complete list of authors is available with the full text of this letter at NEJM.org.

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Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Sjoding MW, Dickson RP, Iwashyna TJ, Gay SE, Valley TS. Racial bias in pulse oximetry measurement. N Engl J Med 2020;383:2477-8. DOI: 10.1056/NEJMc2029240

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Additional Methods Description

The pulse oximeter type (transmittance-mode versus reflectance-mode) used in SpO₂ measurements was not recorded for either cohort. Since measurements were repeated among individual patients, we used “cluster-robust” standard errors when determining 95% confidence intervals (95%CI) for occult hypoxemia rates, *ie* the vce(cluster) command in Stata, version 16¹. We compared the extent to which SpO₂ measurements in Blacks and Whites were able to discriminate hypoxemia (SaO₂ < 88%) by estimating the areas under the receiver operator characteristic curve (AUROC) in each race. To account for clustering when estimating AUROC 95% confidence intervals or when comparing the difference in AUROCs, we drew 1000 cluster bootstrap samples (drawing samples at the patient-level with replacement).² All statistical analyses were performed in Stata, version 16 (College Station, TX).

Subgroup Analysis

We conducted two subgroup analyses to evaluate whether heavy smoking or diabetes might influence the primary results. First, in the UM cohort, after excluding SpO₂-SaO₂ pairs with associated carboxyhemoglobin levels > 2%, 63 of 649 (9.7%, 95%CI 7.3-12.9%) measurements in Blacks and 62 of 2,234 (2.8%, 95%CI 2.0-3.8%) measurements in Whites with SpO₂ between 92 and 96% had SaO₂ less than 88%. Second, in the UM cohort, after excluding patients with diabetes, as identified through the Charlson Comorbidity Index ICD10 diagnosis codes for diabetes during the hospitalization³, 38 of 305 (12.5%, 95%CI 9.1-18.1%) measurements in Blacks and 56 of 1,880 (3.2%, 95%CI 2.0- 4.5%) measurements in Whites with SpO₂ between 92 and 96% had SaO₂ less than 88%.

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EXHIBIT U



Blood Oxygen app on Apple Watch

October 2022

Overview

Apple Watch — Series 6 or later, excluding Apple Watch SE¹ — is capable of measuring oxygen saturation of arterial hemoglobin (SpO₂) for fitness and wellness applications. The Apple Watch optical system uses a combination of light emitters and light sensors to take the blood oxygen measurement. A blood oxygen level represents the percentage of arterial hemoglobin in red blood cells that carry the oxygen from the lungs to the rest of the body. Blood oxygen is an established measure of overall wellness. This paper provides a detailed description of the Blood Oxygen feature on Apple Watch, including its testing and accuracy validation.

Introduction

The Blood Oxygen app on Apple Watch analyzes signals generated by sensors to provide estimates of the functional hemoglobin oxygen saturation of arterial blood using pulse oximetry technology. As public awareness of blood oxygen has increased, so too has demand for pulse oximeters, which has elevated the importance of describing device accuracy and how blood oxygen is determined. The purpose of this white paper is to share additional information about the Blood Oxygen feature on Apple Watch, its development, and its reading accuracy.

Wellness uses of the app include measurements while hiking and trekking at varying altitudes and awareness of one's natural or baseline measurements. Many parameters can affect blood oxygen, including oxygen concentration in the air that a user breathes. At higher altitude and lower barometric pressure, the fractional content of oxygen in inspired air decreases, which affects the blood oxygen saturation. Knowing the saturation can help users gauge activity and effort when traveling to or hiking at altitude. The ability to understand and trend blood oxygen levels can also be a helpful exercise metric for users. Normal physiologic response to exercise in a healthy person is maintaining or increasing SpO₂.

The Blood Oxygen app operates in two modes: on-demand spot checks that users initiate manually, and intermittent background measurements taken during low-movement conditions without requiring any user action. The app attempts to collect optical sensor data to generate SpO₂ readings when the user is stationary with the wrist in the desired posture for a short time period. Generating background spot check measurements when predefined conditions are met is referred to as "opportunistic" data acquisition. The Apple Watch irregular rhythm notification feature also uses this type of data acquisition method. It is important to note that the intermittent background measurements taken by Apple Watch are not the same as the continuous second-by-second measurement capability commonly available with bedside pulse oximeters.

SpO₂ Technology

The Blood Oxygen feature on Apple Watch measures SpO₂ using conventional pulse oximetry methods: It shines red and near-infrared (IR) light into blood-perfused tissue, detects and processes the reemitted light photo-signals into respective photoplethysmograms (PPGs) that track the heartbeat-induced pulsations, determines the red-to-IR modulation ratio, and translates this into units of % SpO₂ through a predefined mapping relationship. Blood fully saturated with oxygen appears bright red and transitions to a darker brown color as oxygenation falls. The modulation ratio measured in pulse oximetry correlates with the color of the tissue's pulsing arterial blood and is thus used for determining SpO₂ — an estimate of the blood's true oxygenation as measured from an arterial blood draw, also known as the SaO₂ value.

The Apple Watch back crystal includes an array of light emitter and detector apertures configured as a "reflectance" sensor; emitted light scatters through the perfused tissues beneath Apple Watch, with a portion of that light reemerging and striking photodetectors along the same surface. The light sources used by the Blood Oxygen app and shared with other health features on Apple Watch comprise red, IR, and green LEDs operating at wavelengths of approximately 660, 850, and 525 nm, respectively.

For best results, Apple Watch should be worn snugly but comfortably. The back crystal should be approximately centered on the wrist, and it should be in complete contact with the soft tissue at the back of the wrist, farther up the arm than — and not touching — the ulnar styloid (wrist bone).

Pulse signals are smaller at the wrist than at the fingers and other conventional SpO₂ device probe sites due to differences in local vasculatures. Users should remain still and relaxed when manually taking readings, as with other pulse oximeters when pulses are weak. Apple Watch initiates intermittent spot checks automatically when it senses that the user is similarly still and that the wrist is in a proper position (the arm is generally horizontal and the palm is facing down).



Development

During the development and evaluation of the Blood Oxygen feature, Apple collected data in multiple institutional review board (IRB)–approved studies involving many hundreds of participants who consented to the collection and use of their data for this purpose. These studies included controlled laboratory studies and supervised data collection sessions under a variety of user behaviors, cardiorespiratory conditions, and ambient environments, including real or simulated altitudes to span the 70–100% blood oxygen saturation range (based on conventional finger pulse oximetry or arterial blood sampling).

Subject pools included a wide range of skin types and tones to ensure that the sensor platform can accommodate the full range of users and maintain accuracy. At the wavelengths that Apple Watch uses, melanin is a strong light absorber — particularly in the green and red part of the spectrum — potentially making PPG measurements more difficult in users with darker skin tones. To account for this, the Apple Watch sensing platform senses the amount of detected light signals, and it automatically adjusts the LED current (and hence the light output), photodiode gain (sensitivity to light), and sampling rate to ensure adequate signal resolution across the range of human skin tones.

Motion and low blood perfusion can obscure the underlying heartbeat-induced pulsatile signals, and both are well-known challenges to pulse oximeter reading accuracy and availability. Arm position can also impact SpO₂ readings because it can create a condition of “venous pulsation” where local arterial and venous blood compartments modulate with the cardiac cycle. Venous blood usually has substantially lower oxygen saturation, so its contribution could falsely lower SpO₂ measurements. To ensure accurate reporting, the Blood Oxygen app withholds readings when it determines that the PPG signals from Apple Watch are inadequate or that positional or movement conditions are unsuitable for reliable SpO₂ readings. If this occurs during a user-initiated session, a message displays indicating the potential reasons.

Performance Accuracy

Pulse oximeter accuracy is described in terms of the agreement between the device-reported SpO₂ and the true SaO₂ value, which is the gold standard reference for arterial blood oxygenation. Per the pulse oximeter International Standard² and FDA Guidance,³ accuracy is computed as the root-mean-square of the pooled SpO₂–SaO₂ differences (A_{rms}) observed in a population of subjects spanning the full range of 70–100% SaO₂. Because measurements are statistically distributed, only about two-thirds of readings can be expected to fall within $\pm A_{rms}$ of the SaO₂ value. The standardized test methodology comprises a desaturation study conducted “under well-controlled, optimal laboratory conditions”² on at least 10 healthy adult subjects, as described in the ISO and FDA references noted above.

The Apple team finalized and prospectively validated the algorithm’s Ratio-to-SpO₂ mapping function in a two-part study that included SaO₂ values from arterial blood sampling. Pooling and analyzing the paired observations from this development data, as described below, offers a perspective of the accuracy of the SpO₂ provided by Apple Watch when tested in the same manner as hospital-use pulse oximeters.

Data Collection

Apple contracted with a lab facility experienced in conducting similar studies under its IRB-approved protocol. Overall, 50 healthy adult subjects were enrolled, and each signed an informed consent form to allow the collection of their data for the purposes of this study. Subjects ranged from ages 19 to 40 (a mean of 26.6 years), split evenly by biological sex, and covering a wide range of skin tones (eight subjects had dark skin characterized visually as Fitzpatrick scale type V or VI). Each subject was fitted with a radial artery cannula, and periodic blood samples were drawn for analysis in a hemoximeter to determine SaO₂ spectroscopically.

On the other arm, each subject wore an Apple Watch Series 6 with an Apple Watch Sport Band near the center of the wrist, close but proximal of the styloid bone, with snug but comfortable band tightness. Sixteen watches — eight large (44mm case) and eight small (40mm case) — were distributed evenly across 48 of the subjects, independent of wrist size. (Two watches were cycled again for the remaining two subjects.) Hypoxia was induced in a stepwise manner by varying the subjects’ inspired oxygen fraction, with blood samples taken during periods of stable saturation as indicated in real time by a pair of monitoring pulse oximeters using finger probes.

Raw unprocessed watch signals were recorded continuously throughout the sessions using proprietary data collection software, independent of the blood sampling. At the end of each session, recorded signals were downloaded from Apple Watch for offline processing using the Blood Oxygen app algorithm (with watchOS 8). SpO₂ values were computed using individual 15-second segments of watch signals; for direct comparisons with SaO₂, segment start times were aligned with the beginning of each respective blood draw. Study data was collected in two parts — the first 26 subjects’ signals contributed to the algorithm’s Ratio-to-SpO₂ mapping function (calibration), and the final 24 subjects’ data was used to validate those results and characterize the system’s A_{rms} accuracy against a blood reference. The processing and analysis of this collected data were conducted solely by Apple.

Performance characteristics were evaluated across the 70–100% SaO₂ span, as well as a narrower 85–95% SaO₂ span that encompasses the region generally associated with the onset of less-than-normal oxygen saturation. Five subject groupings are presented: light skin (Fitzpatrick I–IV), dark skin (Fitzpatrick V–VI), male, female, and overall. The measures comprise A_{rms} and its 95 percent confidence interval (CI) computed by bootstrapping among the subjects, mean SpO₂–SaO₂ difference and bootstrapped 95 percent CI, upper and lower limits of agreement (LOA) computed per the Bland-Altman method accounting for repeated measures,⁴ and SpO₂ reading availability.

Results

Figure 1 below illustrates a study session for one of the subjects. Each subject was exposed to two desaturation cycles from ~100% to ~70% SaO₂, with a recovery and rest in the middle.

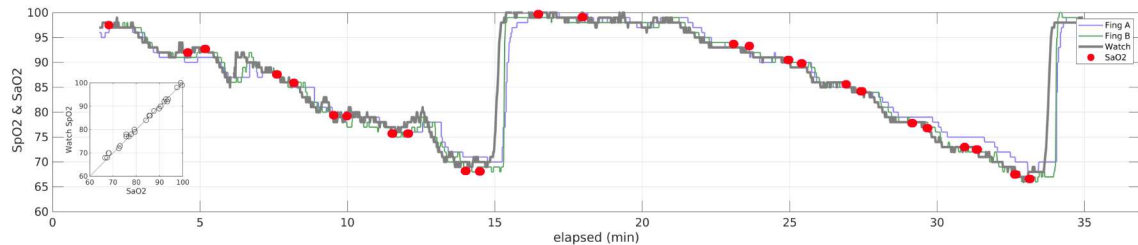


Figure 1. This trend plot represents one of the sessions from the validation data set. SpO₂ trends for the monitored fingers — Fing A and Fing B — and for Apple Watch are shown by the blue, green, and gray lines, respectively. Sampled blood SaO₂ values are indicated by the red dots. The inset to the left plots Apple Watch SpO₂ compared with SaO₂ during this session.

All 50 subject sessions provided data. Only valid data, as assessed before the analysis, was included: when blood draws were obtained while saturation was stable, when SaO₂ values were available and uncorrupted, and when the wrist was still and oriented properly. Overall, there were 1,020 such observation periods with sampled SaO₂ \geq 70%. Simultaneous SpO₂ values were available in 966 of these periods (514 and 452 from the first and second sets, respectively, with 54 instances of the algorithm deeming PPG signals to be inadequate), resulting in an overall reading availability of 94.7 percent. The median number of paired observations per subject session was 21 (range of 6–25), with four contributing fewer than 10 pairs. Performance results for the two data sets are shown in table 1 and figures 2 and 3.

The 70–100% A_{rms} was 1.77% SpO₂ in the first 26 subjects and 2.18% SpO₂ in the final 24-subject validation set. Linear regression is $y = 0.961x + 3.382$ for the calibration data set and $y = 0.959x + 3.906$ for the validation set; confidence intervals for these two regression lines overlap across the entire span. With comparable regressions in the two data sets, and with overlap in respective A_{rms} and mean difference confidence intervals, performance comparisons across gender and skin tone are presented for the pooled data to achieve higher statistical power within each subgroup, as shown in table 2 and figures 4 and 5.

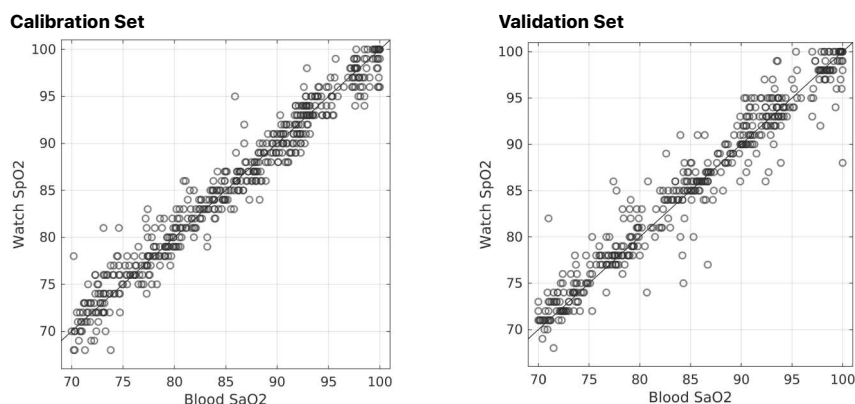


Figure 2. These scatterplots compare paired Apple Watch SpO₂ with SaO₂ for the calibration (N=26 subjects) and validation (N=24 subjects) data sets.

Table 1. Summary Statistics over the 70–100% and 85–95% SaO₂ Spans

SaO ₂ Span	Data Set	#Subjects / #Pairs / #Tries	A_{rms} [95% CI]	Mean Difference [95% CI]	95% LOA
70–100%	Calibration	26 / 514 / 551	1.77 [1.46–2.11]	+0.06 [–0.36–0.52]	–3.39–3.51
	Validation	24 / 452 / 469	2.18 [1.55–2.84]	+0.37 [–0.28–0.97]	–3.85–4.59
85–95%	Calibration	26 / 194 / 203	1.67 [1.37–2.00]	–0.14 [–0.61–0.32]	–3.44–3.17
	Validation	24 / 175 / 177	2.05 [1.41–2.63]	+0.24 [–0.34–0.80]	–3.79–4.26

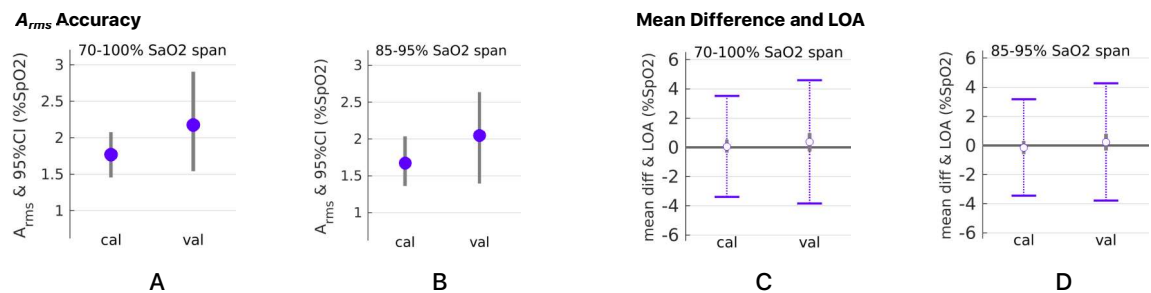


Figure 3. Charts A and B show A_{rms} and the associated 95 percent confidence intervals for the calibration and validation data sets over the two SaO₂ spans. Charts C and D show the mean SpO₂–SaO₂ differences indicated by the open circles for the two data sets and spans, with gray bars indicating the 95 percent confidence intervals for the means; 95 percent LOA for the individual observed differences are indicated by dotted lines and upper and lower blue lines.

Below, figure 4 provides plots for paired data broken out by subgroups of male, female, light skin tones, and dark skin tones. Figure 5 and table 2 summarize the performance characteristics over the 70–100% and 85–95% SaO₂ spans across each subgroup and overall.

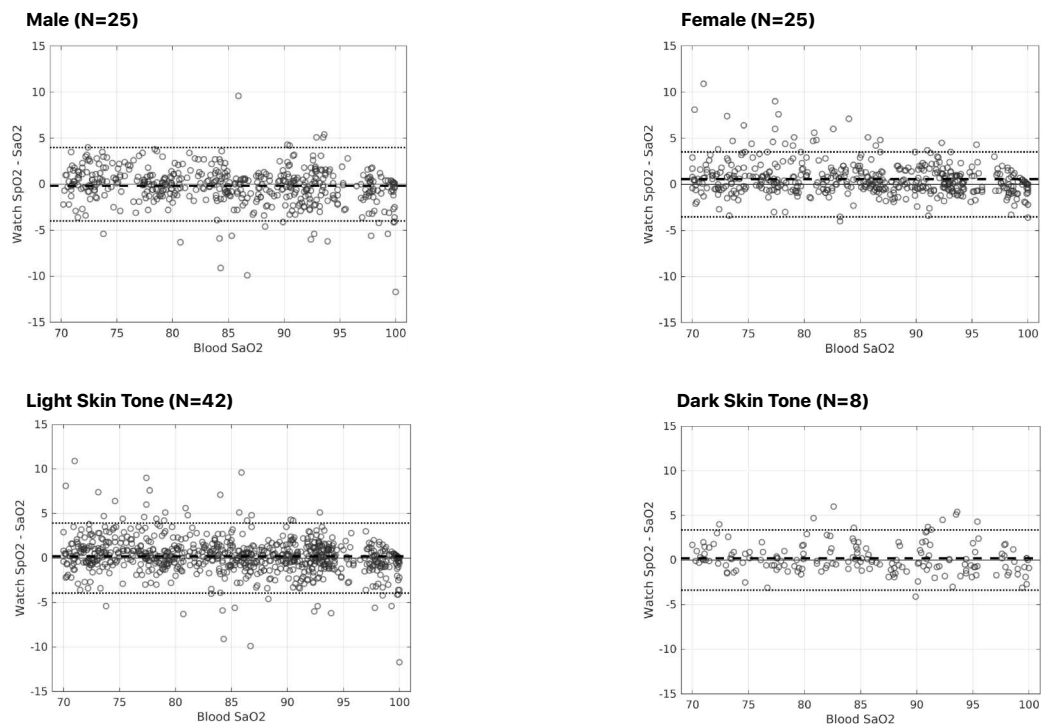


Figure 4. Modified Bland-Altman plots illustrate the paired Apple Watch SpO₂ and SaO₂ data in each of the four subgroups over the 70–100% span. The mean difference is shown by the dashed lines, and 95 percent LOA is shown by the dotted lines. These plots use decimal precision SpO₂ to better distinguish overlapping data.

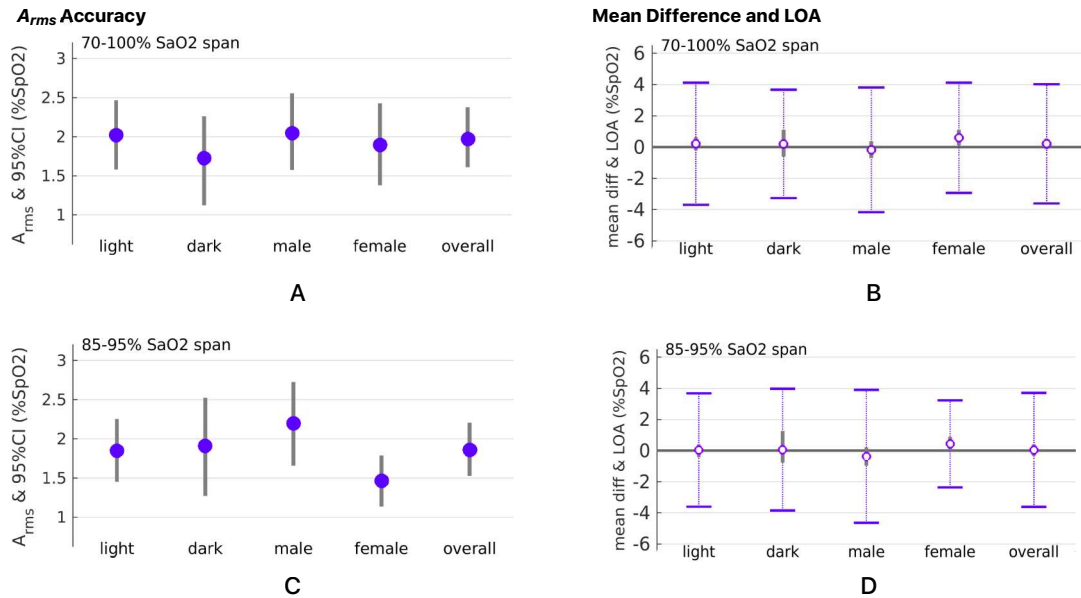


Figure 5. These charts compare performance for the data in the 70–100% and 85–95% SaO₂ across the five groups: light skin tone subjects, dark skin tone subjects, male subjects, female subjects, and overall. A_{rms} is shown in charts A and C, with the gray error bars indicating 95 percent CI. The mean SpO₂–SaO₂ differences are shown in charts B and D for the two spans by the open circles, with the gray bars indicating 95 percent CI; 95 percent LOA in the observed differences are indicated by the upper and lower blue lines.

Table 2. Performance Observations Overall and in Subgroups

SaO ₂ Span	Subgroup	#Subjects / #Pairs / #Tries	A_{rms} [95% CI]	Mean Difference [95% CI]	95% LOA
70–100%	Overall	50 / 966 / 1020	1.97 [1.61–2.38]	0.21 [-0.13–0.55]	-3.61–4.02
	Light skin	42 / 794 / 843	2.02 [1.58–2.47]	0.21 [-0.21–0.63]	-3.70–4.12
	Dark skin	8 / 172 / 177	1.73 [1.12–2.26]	0.20 [-0.61–1.11]	-3.26–3.67
	Male	25 / 486 / 515	2.05 [1.57–2.56]	-0.17 [-0.71–0.36]	-4.16–3.81
	Female	25 / 480 / 505	1.90 [1.38–2.43]	0.59 [0.12–1.11]	-2.93–4.11
85–95%	Overall	50 / 369 / 380	1.86 [1.53–2.21]	0.04 [-0.35–0.40]	-3.62–3.70
	Light skin	42 / 309 / 320	1.85 [1.45–2.25]	0.04 [-0.42–0.40]	-3.60–3.68
	Dark skin	8 / 60 / 60	1.91 [1.27–2.53]	0.06 [-0.77–1.27]	-3.85–3.97
	Male	25 / 180 / 185	2.20 [1.66–2.73]	-0.37 [-0.97–0.21]	-4.64–3.90
	Female	25 / 189 / 195	1.47 [1.14–1.79]	0.43 [0.01–0.89]	-2.36–3.23

Discussion

The Blood Oxygen app on Apple Watch provides accurate and validated on-demand and background measurements of SpO₂. The observed 50-subject A_{rms} accuracy of 1.97% SpO₂ is within the typical specification limits defined in the U.S. FDA Guidance document ($\leq 3.0\%$ or $\leq 3.5\%$ SpO₂, depending on sensor type)³ and the ISO standard limit ($\leq 4\%$ SpO₂)² when tested according to the methods described above. This A_{rms} value is also similar to those of medical-grade devices used in hospitals when tested in the same manner.

Accuracy, LOA, and mean SpO₂–SaO₂ difference (bias) were comparable across the four subgroups and did not differ statistically from one another in either of the SaO₂ spans. Recent literature has raised concerns of significant SpO₂ reading bias and degraded accuracy in Black patients. In the subjects included in our controlled lab study, we did not observe a skin-tone dependence in A_{rms} or mean reading differences when compared with blood.

Equivalent to conventional pulse oximetry, performance can be affected if the sensing optics do not make complete contact with the skin or are worn very tightly. These suboptimal conditions commonly result in unavailable readings, but they can also affect accuracy — creating SpO₂ readings that may overestimate or underestimate SaO₂. Much of the outlier scatter seen in figure 2 resulted from three subject sessions — one in the first data set and two in the second — in which the watch was not worn with recommended snugness. One of these sessions (a male subject with well-perfused light skin) is highlighted in figure 6, with the observations overlaid on the remaining data. The other two noted sessions (both female subjects with well-perfused light skin) account for 10 of the high-reading outliers seen with SaO₂ < 85%. In the absence of these three data sets, the overall pooled 70–100% A_{rms} improves from 1.97% to 1.67% SpO₂.

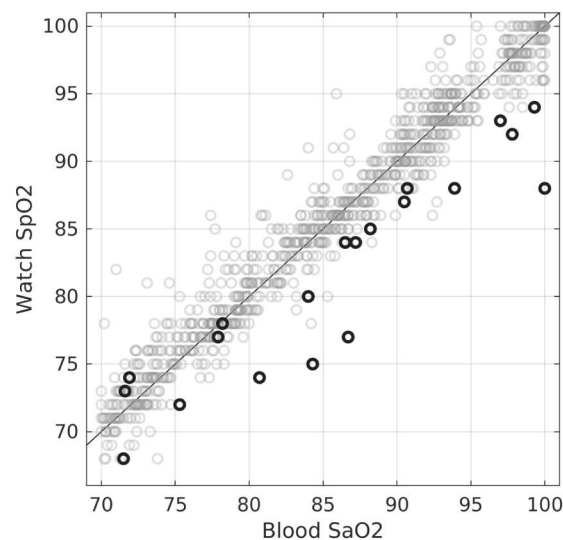
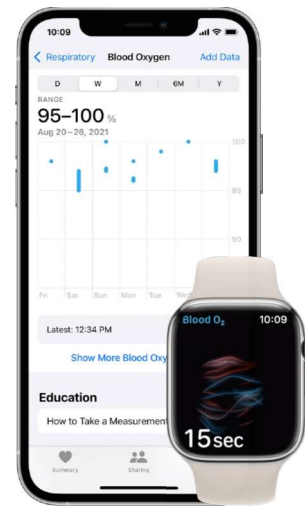


Figure 6. Observations from one subject session in which the watch was not worn with recommended snugness are shown by the dark points overlaid on the overall data shown in light gray.

Factors like interference from the wrist bone, a loose or overly tight watch band, and low skin perfusion may make it difficult to obtain readings from Apple Watch. Performance may be improved by moving Apple Watch farther away from the wrist bone, ensuring that the band is snug, and avoiding cold wrists and hands. When taking on-demand measurements, it is also important for users to be still and relaxed to obtain an SpO₂ reading.

HealthKit

HealthKit provides a central repository for health and fitness data on iPhone and Apple Watch. A user's background and on-demand SpO₂ values are displayed in the Health app and can be viewed by day, week, month, or year. Values taken at barometric pressures generally found at altitudes above approximately 5000 feet are annotated "high elevation environment." Values taken during sleep are also labeled. Understanding individual level trends allows the user to see the variability in their average values, as well as highs and lows and when those values occurred (for example, during air travel or sleep).



Conclusion

Apple Watch includes a range of features that focus on health, fitness, safety, and staying connected. The Blood Oxygen app on Apple Watch is an accurate wrist-based pulse oximeter capable of both on-demand and background measurements. The data is available in the Health app on iPhone, allowing users to track values and trends. Features that track activity, heart rate, cardio fitness, and SpO₂ make Apple Watch a powerful wellness device for all users. Its blood oxygen measurements are accurate, as described in this white paper, and can be helpful in assessing general wellness.

¹Based on availability as of October 2022. ²ISO. 2017. "ISO 80601-2-61: Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment," second edition. Corrected February 2018. www.iso.org/standard/67963.html. ³FDA. "Pulse Oximeters - Premarket Notification Submissions [510(k)s] - Guidance for Industry and Food and Drug Administration Staff." Regulatory Information. Guidance document issued March 4, 2013. fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug. ⁴Bland, J. Martin, Douglas G. Altman. 2007. "Agreement between methods of measurement with multiple observations per individual." *Journal of Biopharmaceutical Statistics* 17, no. 4: 571-82. doi.org/10.1080/10543400701329422.

EXHIBIT V

From: [Benjamin Luehrs](#)
To: [Jared Bunker](#)
Cc: [Apple Masimo Service](#); [Moore, David E.](#); [Palapura, Bindu A.](#); [Jack Phillips](#); [Lit MASIMOL.1594L](#); [Greenfield, Leon](#); [Milici, Jennifer](#); [Kerri-Ann Limbeek](#); [Megan C. Haney](#); [Vote, Dominic](#); [Ford, Mark](#); [Lit MASIMOL.1593L](#); [Jordan Malz](#); [Brian Horne](#); [Peter Magic](#)
Subject: Apple v. Masimo 1377 (D. Del.) - Draft Rule 26(f) report and proposed schedule
Date: Friday, February 17, 2023 6:27:00 PM
Attachments: [2023-02-17 - Draft Apple-Masimo \(Design\) 26f Report.docx](#)
[2023-02-17 - Draft Proposed Scheduling Order.docx](#)

Counsel,

Enclosed please find Apple's draft Rule 26(f) report and Proposed Scheduling Order for the design case (1377). Please send us Defendants' portions. If there are any issues to further discuss, the parties can meet and confer again next week.

Sincerely,
Ben

Ben Luehrs | **DESMARAIS LLP**

230 Park Avenue | New York, NY 10169

T: (212) 808-2952 | M: (203) 962-6557

E: bluehrs@desmaraisllp.com

ATTACHMENT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

APPLE INC.,

Plaintiff,

v.

MASIMO CORPORATION and
SOUND UNITED, LLC,

Defendants.

C.A. No. 22-01377-MN

JURY TRIAL DEMANDED

MASIMO CORPORATION,

Counterclaimant,

v.

APPLE INC.,

*Counterclaim
Defendant.*

RULE 26(F) REPORT

David E. Moore (#3983)
Bindu A. Palapura (#5370)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000

*Attorneys for Plaintiff and
Counterclaim-Defendant Apple Inc.*

February XX, 2023

RULE 26(F) REPORT

Counsel for Plaintiff and Counterclaim-Defendant Apple Inc. (“Apple”), Defendant and Counterclaimant Masimo Corporation (“Masimo”), and Defendant Sound United, LLC (“Sound United”) (Masimo and Sound United individually and collectively referred to as “Defendants”) jointly submit this report concerning their meet and confer pursuant to Rule 26(f) of the Federal Rules of Civil Procedure. On February 9, 2023, via telephone conference call, the following counsel conferred on the topics outlined in this report and discovery plan:

- Apple: David Moore, Peter Magic, Cosmin Maier, Ben Luehrs, Jordan Malz, Kerri-Ann Limbeek, Jamie Kringstein, Carson Olsheski
- Defendants: John Phillips, Jared Bunker, Steve Larson, Brian Horne

The parties discussed all topics set forth in Federal Rule of Civil Procedure 26(f), Local Rule 16.1, the Court’s “Default Standard for Discovery, Including Discovery of Electronically Stored Information,” and the Court’s Proposed Scheduling Order for Non-ANDA Patent cases.

The parties have contradicting views regarding how this case (Case No. 1:22-cv-1377-MN, hereinafter, the “Design Case”) and another case between the parties (Case No. 1:22-cv-1378-MN, hereinafter, the “Utility Case”) should proceed and were not able to reach agreement on a schedule or discovery limits. In short, Apple filed a motion to expedite trial in this case (Design Case, D.I. 44), which Defendants oppose; and Defendants contend that the Design Case and the Utility Case should be consolidated.

I. APPLE’S POSITION

As set forth in Apple’s “Opening Brief In Support Of Its Motion For An Expedited Trial,” D.I. 45 (“Motion to Expedite”), Apple believes that an expedited trial is feasible, necessary to mitigate irreparable harms to Apple caused by Defendants’ willful infringement, and not unduly prejudicial to Defendants. *See* D.I. 45 at 1. The Proposed Scheduling Order (Ex. **XX**) attached hereto includes two alternative schedules based on the outcome of that Motion to Expedite. **Schedule A**¹ reflects Apple’s proposed schedule if the Court grants the Motion to Expedite and sets trial approximately eight months after the Court’s decision on that motion. **Schedule B** reflects Apple’s proposed schedule if the Court denies the Motion to Expedite and sets trial approximately 12 months after the Court’s decision on that motion.

As explained in Apple’s Motion to Expedite, Apple does not believe that claim construction is necessary in this case and proposes bifurcating damages to further streamline the issues for expedited discovery and trial. *See* D.I. 45 at 1. Apple’s proposal therefore includes separate discovery limits for liability issues.² If the Court grants the Motion to Expedite and bifurcates damages, Apple proposes proceeding according to Schedule A with the discovery limits for liability set forth in the Proposed Scheduling Order. After the expedited trial on liability concludes, the parties can meet and confer regarding a separate schedule for the damages phase if necessary at that time. If the Court grants the Motion to Expedite but does not bifurcate damages, Apple proposes proceeding on the same expedited Schedule A but using the alternative discovery limits in the Proposed Scheduling Order for a non-bifurcated trial.

If the Court denies the Motion to Expedite, Apple proposes proceeding according to Schedule B, which sets trial approximately 12 months after the Court’s decision on that motion.

¹ Schedule A was attached to Apple’s Motion to Expedite as Exhibit R.

² Liability issues include infringement, validity, willfulness, and injunctive relief.

Schedule B is consistent with the Court's schedule in *Gavrieli Brands LLC v. Soto Massini (USA) Corp. et al.*, C.A. No. 18-462-GMS, D.I. 44-45 ("Scheduling Order"), in which this Court set trial within 10 months of the scheduling order in a design patent case (but did not schedule claim construction). Even if the Motion to Expedite is denied, Apple still does not believe that claim construction is necessary in this design case. In the event the Court determines that claim construction is necessary, the claim construction issues will be minimal and thus can proceed in parallel with fact discovery. Schedule B includes claim construction deadlines for that scenario.

Apple believes that the Design Case and the Utility Case should not be consolidated at least because the two cases involve different questions of law and fact, and consolidation will exacerbate the irreparable harm to Apple caused by Defendants' willful infringement and militate against an expeditious and economical resolution of this case. If the Court decides to consolidate the Design Case and the Utility Case, however, Apple proposes that the alternative discovery limits in the Proposed Scheduling Order for a non-bifurcated trial be added to any discovery limits in the Utility Case, and that the case proceed according to the schedule proposed by Apple in that case.

Apple respectfully requests an opportunity to revise its Proposed Scheduling Order in light of the Court's rulings on the pending motions and scheduling disputes.

II. DEFENDANTS' POSITION

Dated: February XX, 2023

Respectfully submitted,

David E. Moore (#3983)

[MASIMO SIGNATURE BLOCK]

Bindu A. Palapura (#5370)

POTTER ANDERSON & CORROON LLP

Hercules Plaza, 6th Floor

1313 N. Market Street

Wilmington, DE 19801

Tel: (302) 984-6000

dmoore@potteranderson.com

bpalapura@potteranderson.com

OF COUNSEL:

John M. Desmarais

Jordan N. Malz

Cosmin Maier

Kerri-Ann Limbeek

Jamie L. Kringstein

DESMARAIS LLP

230 Park Avenue

New York, NY 10169

Tel: (212) 351-3400

jdesmarais@desmaraisllp.com

jmalz@desmaraisllp.com

cmaier@desmaraisllp.com

klimbeek@desmaraisllp.com

jkringstein@desmaraisllp.com

Peter C. Magic

DESMARAIS LLP

101 California Street

San Francisco, CA 94111

Tel: (415) 573-1900

pmagic@desmaraisllp.com

*Attorneys for Plaintiff and
Counterclaim-Defendant Apple Inc.*

ATTACHMENT B

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

APPLE INC.,

Plaintiff,

v.

MASIMO CORPORATION and
SOUND UNITED, LLC,

Defendants.

C.A. No. 22-1377-MN

MASIMO CORPORATION,

Counter-Claimant,

v.

APPLE INC.

Counter-Defendant.

[PROPOSED] SCHEDULING ORDER [PATENT, NON-ANDA]¹

This _____ day of _____, 20____, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

¹ As stated in the Rule 26(f) Report, Apple includes herein two alternative schedules based on the outcome of Apple's Motion For An Expedited Trial. D.I. 44 ("Motion to Expedite"). **Schedule A** reflects Apple's proposed schedule if the Court grants the Motion to Expedite and sets trial approximately eight months after the Court's decision on that motion. **Schedule B** reflects Apple's proposed schedule if the Court denies the Motion to Expedite and sets trial approximately 12 months after the Court's decision on that motion.

Schedules A and B include deadlines based on the date of the order on the Motion to Expedite. Apple proposes that the parties submit a revised schedule with concrete dates following the Court's decision on that motion.

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within five (5) days of the date the Court enters this Order. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at <http://www.ded.uscourts.gov> (see Other Resources, Default Standard for Discovery). The parties agree to meet and confer concerning issues related to ESI and to address such issues via a separate proposed order.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before [**Schedules A & B - 4 weeks after Order on Motion For An Expedited Trial**]. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 8(g) and 9.

3. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date the Court enters this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 8(g) below.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to

this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

5. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of all briefs and any other document filed in support of any briefs (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

6. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

7. Disclosures. Absent agreement among the parties, and approval of the Court:

(a) By [**Schedules A & B - 5 days after Order on Motion For An Expedited Trial**], Plaintiff shall identify the accused product(s), including accused methods and systems, and its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s). Plaintiff shall also produce the file history for each asserted patent.

(b) By [**Schedules A & B - 2 weeks after Order on Motion For An Expedited Trial**], Defendant shall produce core technical documents related to the accused product(s), sufficient to show how the accused product(s) work(s), including but not limited to non-publicly available operation manuals, product literature, schematics, and specifications. Defendant shall also produce sales figures for the accused product(s).

(c) By **[Schedules A & B - 2 weeks after Order on Motion For An Expedited Trial]**, Plaintiff shall produce an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes.

(d) By **[Schedules A & B - 3 weeks after Order on Motion For An Expedited Trial]**, Defendant shall produce its initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

(e) By **[Schedules A & B - 8 weeks after Order on Motion For An Expedited Trial]**, Plaintiff shall provide final infringement contentions.

(f) By **[Schedules A & B - 9 weeks after Order on Motion For An Expedited Trial]**, Defendant shall provide final invalidity contentions.

8. Discovery.² Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **[Schedule A - 10 weeks after Order on Motion For An Expedited Trial; Schedule B – 20 weeks after Order on Motion For An Expedited Trial]**.

(b) Document Production. Document production shall be substantially complete by **[Schedule A - 7 weeks after Order on Motion For An Expedited Trial; Schedule B – Technical document production shall be substantially complete by 7 weeks after Order on Motion For An Expedited Trial, and all document production shall be substantially complete 12 weeks after Order on Motion For An Expedited Trial]**. A maximum of 50

² As explained in Apple's Motion to Expedite, Apple proposes bifurcating damages to further streamline the issues for expedited discovery and trial. *See* D.I. 45 at 1. Apple's proposal therefore includes separate discovery limits for liability issues, including infringement, validity, willfulness, and injunctive relief. If the Court decides to bifurcate damages, Apple proposes proceeding with the discovery limits for liability set forth herein. If the Court does not bifurcate damages, Apple proposes using the alternative discovery limits herein for a non-bifurcated case.

requests for production are permitted for each side for liability issues and a maximum of 75 requests for production are permitted for each side if the case is not bifurcated.

(c) Requests for Admission. A maximum of 30 requests for admission are permitted for each side for liability issues and a maximum of 45 requests for admission are permitted for each side if the case is not bifurcated.

(d) Interrogatories.

i. A maximum of 15 interrogatories, including contention interrogatories, are permitted for each side for liability issues and a maximum of 20 interrogatories, including contention interrogatories, are permitted for each side if the case is not bifurcated.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 35 hours of taking fact testimony by deposition upon oral examination for liability issues and each side is limited to a total of 55 hours of taking fact testimony by deposition upon oral examination if the case is not bifurcated.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a

counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision. The parties agree that depositions of parties and representatives (officer, director, or managing agent) of parties may be deposed in the location that they reside, subject to a showing of good cause for holding the deposition in another location.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before [**Schedule A - 12 weeks after Order on Motion For An Expedited Trial; Schedule B - 22 weeks after Order on Motion For An Expedited Trial**]. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before [**Schedule A - 14 weeks after Order on Motion For An Expedited Trial; Schedule B - 24 weeks after Order on Motion For An Expedited Trial**]. Reply expert reports from the party with the initial burden of proof are due on or before [**Schedule A - 16 weeks after Order on Motion For An Expedited Trial; Schedule B - 26 weeks after Order on Motion For An Expedited Trial**]. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Expert Report Supplementation. The parties agree they will not permit expert declarations to be filed in connection with motions briefing (including case-dispositive motions).³

iii. Objections to Expert Testimony. To the extent any objection to

³ Nothing in this Order shall prohibit any party from submitting a declaration from a testifying expert that merely attaches and incorporates by reference expert reports previously served by that party.

expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court. Briefing on such motions is subject to the page limits set out in connection with briefing of case dispositive motions.

iv. Expert Discovery Cut-Off. All expert discovery in this case shall be initiated so that it will be completed on or before [**Schedule A - 18 weeks after Order on Motion For An Expedited Trial; Schedule B - 28 weeks after Order on Motion For An Expedited Trial**].

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after a reasonable effort pursuant to Local Rule 7.1.1 that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Judicial Administrator to schedule an argument.

iii. On a date to be set by separate order, generally not less than four (4) days prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than three (3) days prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. The parties shall provide to the Court two (2) courtesy copies of its

discovery letter and any other document filed in support of any letter (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

v. Should the Court find further briefing necessary upon conclusion of the conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the conference and will, in that event, cancel the conference.

9. Motions to Amend / Motions to Strike.

(a) Any motion to amend (including a motion for leave to amend) a pleading or any motion to strike any pleading or other document shall be made pursuant to the discovery dispute procedure set forth in Paragraph 8(g) above.

(b) Any such motion shall attach the proposed amended pleading as well as a “redline” comparison to the prior pleading or attach the document to be stricken.

10. Technology Tutorials. Although technology tutorials are not required by the Court, they are appreciated and, if any party chooses to file such a tutorial, it shall be submitted on or before the date that the Joint Claim Construction Brief is filed.

11. Claim Construction Issue Identification.⁴ On [**Schedule B – 5 weeks after Order on Motion For An Expedited Trial**], the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will

⁴ As explained in Apple’s Motion to Expedite, Apple does not believe that claim construction is necessary in this design patent case. Thus, consistent with the Court’s scheduling order in *Gavrieli Brands LLC v. Soto Massini (USA) Corp. et al.*, C.A. No. 18-462-GMS, D.I. 44-45, which did not include claim construction deadlines, Apple did not include claim construction deadlines in Schedule A. However, in the event the Court determines that claim construction is necessary, the claim construction issues will be minimal and thus can proceed in parallel with fact discovery, as provided for in Schedule B.

meet and confer to prepare a Joint Claim Construction Chart to be submitted two weeks prior to service of the opening claim construction brief. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. Intrinsic evidence (including copies of the patent(s) at issue) shall NOT be attached to the joint claim construction chart and, instead, the parties shall include a joint appendix with the joint claim construction brief, and the joint appendix shall include a copy of the patent(s) at issue and portions of all relevant intrinsic evidence that would have otherwise been included with the joint claim construction chart, as well as any additional evidence cited in the parties' briefing.

12. Claim Construction Briefing.⁵ The Plaintiff shall serve, but not file, its opening brief, not to exceed 20 pages, on [**Schedule B - 11 weeks after Order on Motion For An Expedited Trial**]. The Defendant shall serve, but not file, its answering brief, not to exceed 30 pages, on [**Schedule B – 13 weeks after Order on Motion For An Expedited Trial**]. The Plaintiff shall serve, but not file, its reply brief, not to exceed 20 pages, on [**Schedule B - 14 weeks after Order on Motion For An Expedited Trial**]. The Defendant shall serve, but not file, its sur-reply brief, not to exceed 10 pages, on [**Schedule B - 15 weeks after Order on Motion For An Expedited Trial**]. No later than [**Schedule B - 16 weeks after Order on Motion For An Expedited Trial**], the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below. If the joint brief as submitted is more than 80 pages, the parties must certify that the page limits (or equivalent word counts) in the Scheduling Order have been complied

⁵ See footnote 4, *supra*.

with and provide a brief explanation (e.g., formatting issues, listing of agreed-upon terms) as to why the brief is longer than 80 pages.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

[TERM 2]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

13. Hearing on Claim Construction.⁶ Beginning aton **[Schedule B – 19 weeks after Order on Motion For An Expedited Trial]**, the Court will hear argument on claim construction. The parties need not include any general summaries of the law relating to claim construction in their presentations to the Court. The parties shall notify

⁶ See footnote 4, *supra*.

the Court, by joint letter submission, no later than the date on which their joint claim construction brief is filed: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

14. Supplementation. Absent agreement among the parties, and approval of the Court, no later than [**Schedules A & B - 8 weeks after Order on Motion For An Expedited Trial**] the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.

15. Case Dispositive Motions.

(a) All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before [**Schedule A - 19 weeks after Order on Motion For An Expedited Trial; Schedule B - 29 weeks after Order on Motion For An Expedited Trial**] [a date approximately four months prior to the pretrial conference, the four months being calculated from the conclusion of the briefing]. Briefing will be presented pursuant to the Court's Local Rules. No case dispositive motion under Rule 56 may be filed more than ten (10) days before the above date without leave of the Court.

(b) Concise Statement of Facts Requirement. Any motion for summary judgment shall be accompanied by a separate concise statement, not to exceed six (6) pages, which details each material fact which the moving party contends is essential for the Court's resolution of the

summary judgment motion (not the entire case) and as to which the moving party contends there is no genuine issue to be tried. Each fact shall be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

Any party opposing the motion shall include with its opposing papers a response to the moving party's concise statement, not to exceed six (6) pages, which admits or disputes the facts set forth in the moving party's concise statement on a paragraph-by-paragraph basis. To the extent a fact is disputed, the basis of the dispute shall be supported by specific citation(s) to the record. Failure to respond to a fact presented in the moving party's concise statement of facts shall indicate that fact is not in dispute for purposes of summary judgment. The party opposing the motion may also include with its opposing papers a separate concise statement, not to exceed four (4) pages, which sets forth material facts as to which the opposing party contends there is a genuine issue to be tried. Each fact asserted by the opposing party shall also be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

The moving party shall include with its reply papers a response to the opposing party's concise statement of facts, not to exceed four (4) pages, on a paragraph-by-paragraph basis. Failure to respond to a fact presented in the opposing party's concise statement of facts shall indicate that fact remains in dispute for purposes of summary judgment.

(c) Page limits combined with Daubert motion page limits. Each party is permitted to file as many case dispositive motions as desired provided, however, that each ***SIDE*** will be limited to a combined total of 40 pages for all opening briefs, a combined total of 40 pages for all answering briefs, and a combined total of 20 pages for all reply briefs regardless of the number of case dispositive motions that are filed. In the event that a party files, in addition to a case dispositive motion, a Daubert motion to exclude or preclude all or any portion of an expert's

testimony, the total amount of pages permitted for all case dispositive and Daubert motions shall be increased to 50 pages for all opening briefs, 50 pages for all answering briefs, and 25 pages for all reply briefs for each *SIDE*.⁷

16. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

17. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each *SIDE* shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

18. Pretrial Conference. On [Schedule A - Appx. 31 weeks (7 months) after Order on Motion For An Expedited Trial; Schedule B – Appx. 48 weeks (11 months) after Order on Motion For An Expedited Trial], the Court will hold a pretrial conference in Court with counsel

⁷ The parties must work together to ensure that the Court receives no more than a total of 250 pages (i.e., 50 ± 50 ± 25 regarding one side's motions, and 50 ± 50 ± 25 regarding the other side's motions) of briefing on all case dispositive motions and Daubert motions that are covered by this scheduling order and any other scheduling order entered in any related case that is proceeding on a consolidated or coordinated pretrial schedule.

beginning at 9:00 a.m. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order. The parties shall provide the Court two (2) double-sided courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

19. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1 the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms seven (7) business days before the final pretrial conference. This submission shall be accompanied by a courtesy copy containing electronic files of these documents, in Microsoft Word format, which may be submitted by e-mail to mn_civil@ded.uscourts.gov.

20. Trial. This matter is scheduled for a 3 day jury trial beginning at 9:30 a.m. on **[Schedule A - Appx. 35 weeks (8 months) after Order on Motion For An Expedited Trial; Schedule B – Appx. 52 weeks (12 months) after Order on Motion For An Expedited Trial]**, with the subsequent trial days beginning at 9:00 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 4:30 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

21. Judgment on Verdict and Post-Trial Status Report. Within seven (7) days after a

jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict. At the same time, the parties shall submit a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

22. Post-Trial Motions. Unless otherwise ordered by the Court, all ***SIDES*** are limited to a maximum of 20 pages of opening briefs, 20 pages of answering briefs, and 10 pages of reply briefs relating to any post-trial motions filed by that side, no matter how many such motions are filed.

Counsel Shall Provide a Chart of All Relevant Deadlines

Schedule A - Expedited Trial

EVENT	DEADLINE
Deadline for each party to serve initial disclosures pursuant to Rule 26(a)(1) and Default Standard for Discovery (¶1)	5 days after Order on Motion For An Expedited Trial
Deadline for Apple to identify all accused product(s), its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s), and to produce the file history for each asserted patent (¶7(a))	5 days after Order on Motion For An Expedited Trial
Deadline for the parties to file a proposed protective order (¶3)	10 days after Order on Motion For An Expedited Trial
Deadline for parties to disclose: The 10 custodians most likely to have discoverable information in their possession, custody or control, from the most likely to the least likely (Modified Default Standard ¶3(a))	15 days after Order on Motion For An Expedited Trial
Deadline for parties to disclose: A list of the non-custodial data sources that are most likely to contain non-duplicative discoverable information for preservation and production consideration, from the most likely to the least likely (Modified Default Standard ¶3(b))	15 days after Order on Motion For An Expedited Trial
Deadline for the parties to provide the notices identified in (Modified Default Standard ¶3(c))	15 days after Order on Motion For An Expedited Trial
Deadline for Masimo to produce core technical documents related to the accused product(s) sufficient to show how the accused product(s) work (¶7(b))	2 weeks after Order on Motion For An Expedited Trial
Deadline for Apple to serve initial infringement contentions (¶7(c))	2 weeks after Order on Motion For An Expedited Trial
Deadline for Masimo to serve initial invalidity contentions, as well as produce the known related invalidating references (¶7(d))	3 weeks after Order on Motion For An Expedited Trial
Deadline for joinder of other parties and amendment of pleadings (¶2)	4 weeks after Order on Motion For An Expedited Trial
Deadline for the substantial completion of document production (¶8(b))	7 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to finally supplement the identification of all accused products and all invalidity references (¶14)	8 weeks after Order on Motion For An Expedited Trial
Deadline for Apple to serve final infringement contentions (¶7e)	8 weeks after Order on Motion For An Expedited Trial

Deadline for Masimo to serve final invalidity contentions (§7(f))	9 weeks after Order on Motion For An Expedited Trial
Deadline for the close of fact discovery (§8(a))	10 weeks after Order on Motion For An Expedited Trial
Deadline for opening expert reports for each party that bears the initial burden of proof (§8(f)(i))	12 weeks after Order on Motion For An Expedited Trial
Deadline for rebuttal expert reports (§8(f)(i))	14 weeks after S Order on Motion For An Expedited Trial
Deadline for reply expert reports (§8(f)(i))	16 weeks after Order on Motion For An Expedited Trial
Deadline for the completion of expert discovery (§8(f)(iv))	18 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to file all case dispositive and <i>Daubert</i> motions, as well as an opening brief, statement of facts, and affidavits, if any (§15)	19 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to oppose case dispositive and <i>Daubert</i> motions (§15)	21 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to reply to case dispositive and <i>Daubert</i> motions (§15)	22 weeks after Order on Motion For An Expedited Trial
Deadline for parties to file joint pretrial order (§18)	7 days prior to Pretrial on
Deadline for the parties to file proposed jury instructions, voir dire, and verdict forms	7 days prior to Pretrial on
Pretrial Conference	Appx. 31 weeks (7 months) after Order on Motion For An Expedited Trial
Trial	Appx. 35 weeks (8 months) after Order on Motion For An Expedited Trial

Counsel Shall Provide a Chart of All Relevant Deadlines

Schedule B – Non-Expedited Trial⁸

EVENT	DEADLINE
Deadline for each party to serve initial disclosures pursuant to Rule 26(a)(1) and Default Standard for Discovery (¶1)	5 days after Order on Motion For An Expedited Trial
Deadline for Apple to identify all accused product(s), its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s), and to produce the file history for each asserted patent (¶7(a))	5 days after Order on Motion For An Expedited Trial
Deadline for the parties to file a proposed protective order (¶3)	10 days after Order on Motion For An Expedited Trial
Deadline for parties to disclose: The 10 custodians most likely to have discoverable information in their possession, custody or control, from the most likely to the least likely (Modified Default Standard ¶3(a))	15 days after Order on Motion For An Expedited Trial
Deadline for parties to disclose: A list of the non-custodial data sources that are most likely to contain non-duplicative discoverable information for preservation and production consideration, from the most likely to the least likely (Modified Default Standard ¶3(b))	15 days after Order on Motion For An Expedited Trial
Deadline for the parties to provide the notices identified in Modified Default Standard ¶3(c)	15 days after Order on Motion For An Expedited Trial
Deadline for Masimo to produce core technical documents related to the accused product(s) sufficient to show how the accused product(s) work (¶7(b))	2 weeks after Order on Motion For An Expedited Trial
Deadline for Apple to serve initial infringement contentions (¶7(c))	2 weeks after Order on Motion For An Expedited Trial
Deadline for Masimo to serve initial invalidity contentions, as well as produce the known related invalidating references (¶7(d))	3 weeks after Order on Motion For An Expedited Trial
Deadline for joinder of other parties and amendment of pleadings (¶2)	4 weeks after Order on Motion For An Expedited Trial
Deadline to exchange list of claim term(s)/phrase(s) that the parties believe need	5 weeks after Order on Motion For An Expedited Trial

⁸ As explained in footnote 3, *supra*, Apple does not believe that claim construction is necessary in this case. However, Apple has included provisional claim construction deadlines in this Schedule (noted with *) that would apply in the event that the Court believes claim construction is necessary.

construction and proposed constructions* (¶11)	
Deadline for the substantial completion of technical document production (¶8(b))	7 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to finally supplement the identification of all accused products and all invalidity references (¶14)	8 weeks after Order on Motion For An Expedited Trial
Deadline for Apple to serve final infringement contentions (¶7e)	8 weeks after Order on Motion For An Expedited Trial
Deadline for Masimo to serve final invalidity contentions (¶7(f))	9 weeks after Order on Motion For An Expedited Trial
Deadline to file Joint Claim Construction Chart* (¶11)	10 weeks after Order on Motion For An Expedited Trial
Deadline for Plaintiff to serve its opening claim construction brief* (¶12)	11 weeks after Order on Motion For An Expedited Trial
Deadline for the substantial completion of all document production (¶8(b))	12 weeks after Order on Motion For An Expedited Trial
Deadline for Defendants to serve its answering claim construction brief* (¶12)	13 weeks after Order on Motion For An Expedited Trial
Deadline for Plaintiff to serve its reply claim construction brief* (¶12)	14 weeks after Order on Motion For An Expedited Trial
Deadline for Defendants to serve its sur-reply claim construction brief* (¶12)	15 weeks after Order on Motion For An Expedited Trial
Deadline to file Joint Claim Construction Brief* (¶12)	16 weeks after Order on Motion For An Expedited Trial
Claim construction hearing* (¶13)	19 weeks after Order on Motion For An Expedited Trial
Deadline for the close of fact discovery (¶8(a))	20 weeks after Order on Motion For An Expedited Trial
Deadline for opening expert reports for each party that bears the initial burden of proof (¶8(f)(i))	22 weeks after Order on Motion For An Expedited Trial
Deadline for rebuttal expert reports (¶8(f)(i))	24 weeks after Order on Motion For An Expedited Trial
Deadline for reply expert reports (¶8(f)(i))	26 weeks after Order on Motion For An Expedited Trial
Deadline for the completion of expert discovery (¶8(f)(iv))	28 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to file all case dispositive and <i>Daubert</i> motions, as well as an opening brief, statement of facts, and affidavits, if any (¶15)	29 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to oppose case dispositive and <i>Daubert</i> motions (¶15)	31 weeks after Order on Motion For An Expedited Trial
Deadline for the parties to reply to case dispositive and <i>Daubert</i> motions (¶15)	32 weeks after Order on Motion For An Expedited Trial

Deadline for parties to file joint pretrial order (¶18)	7 days prior to Pretrial Conference
Deadline for the parties to file proposed jury instructions, voir dire, and verdict forms	7 days prior to Pretrial Conference
Pretrial Conference	Appx. 48 weeks (11 months) after Order on Motion For An Expedited Trial
Trial	Appx. 52 weeks (12 months) after Order on Motion For An Expedited Trial

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From the Manufacturer



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Conduction Open-Ear...

Withings - Scanwatch - Hybrid
Smartwatch with ECG, heart ra...

Shokz - OpenRun Mini Bone
Conduction Open-Ear...

Apple - AirPods Pro (2nd
generation) - White



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